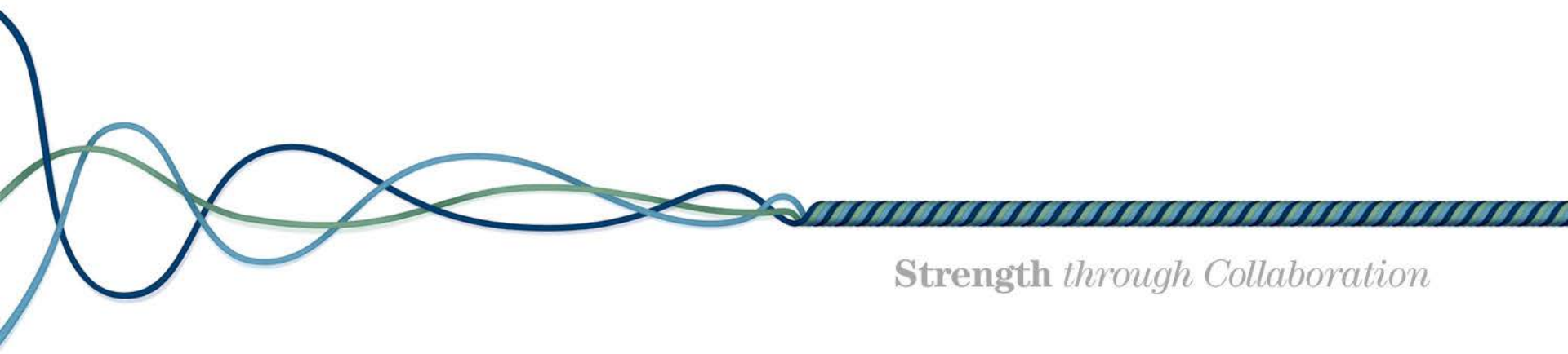
CDISC Public Webinar – Standards Updates and Additions

May 19 2016



Agenda

- ADaMIG v1.1
  - John Troxell, Accenture
- OCCDS v1.0
  - Sandra Minjoe, Accenture

- CDISC Online Education & Event Updates
  - John Ezzell, CDISC

Question & Answer

- ‘Panelist’: Question

OR

- ‘Presentation’: Question

Examples:

John: Where are standards documents in the Wiki?

OR

CDISC: When can we start registering for the International Interchange?

ADaM Implementation Guide v1.1

CDISC Webinar, 2016-05-19

John Troxell
Data Standards Consulting
Accenture Accelerated R&D Services

Strength *through Collaboration*

CDISC

Outline

- Overview of ADaMIG and Related Documents
- Notable Enhancements in Version 1.1
- ADSL
  - Corrections
  - New Variables
- BDS
  - Corrections
  - Removed Variables and Deprecated Variable
  - New Variables
- Acknowledgements

Overview of ADaMIG and Related Documents

Document	ADaMIG v1.0	ADaMIG v1.1
Analysis Data Model (ADaM) v2.1, December 2009	Foundation document for ADaMIG v1.0	Still applicable
ADaM Examples in Commonly Used Statistical Analysis Methods v1.0, December 2011	Written for ADaMIG v1.0	Still applicable
The ADaM Basic Data Structure for Time-to-Event Analyses v1.0, May 2012	Written for ADaMIG v1.0	Still applicable
Update to the first CDISC SDTM/ADaM Pilot Project, January 2013	Written for ADaMIG v1.0	Still applicable
ADaM Data Structure for Adverse Event Analysis v1.0, May 2012	Written for ADaMIG v1.0	Superseded by OCCDS v1.0
ADaM Structure for Occurrence Data (OCCDS) v1.0, February, 2016	Not written for ADaMIG v1.0	Written for ADaMIG v1.1
CDISC ADaM Validation Checks v1.3, March 2015	Written for ADaMIG v1.0	Mostly applicable; v1.4 will be written for ADaMIG v1.1
Define-XML v2.0, March 2013	Applicable	Applicable
Analysis Results Metadata Specification for Define-XML Version 2 v1.0, January 2015	Applicable	Applicable

Notable Enhancements in Version 1.1

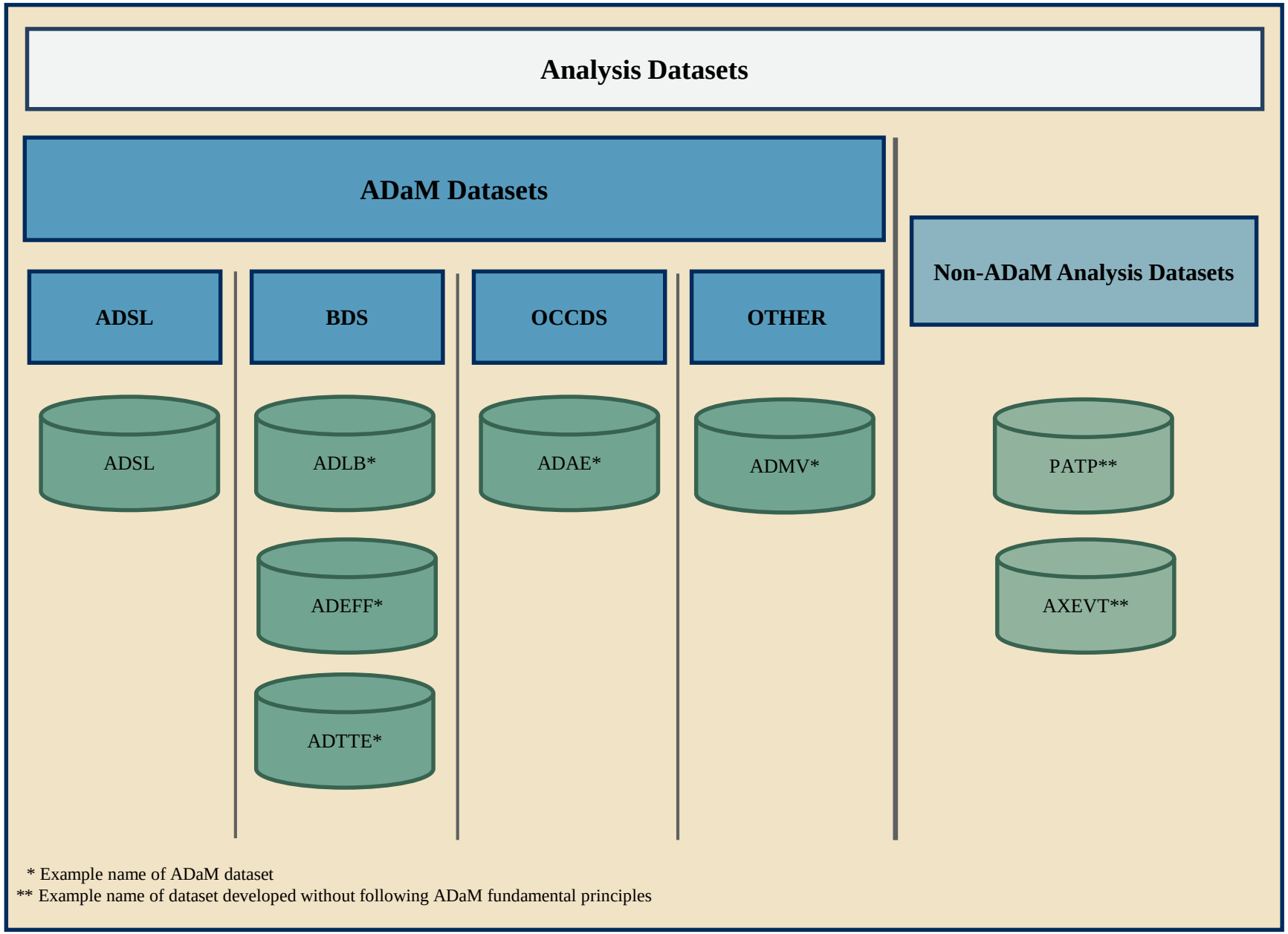
- Main emphasis: clarification of ADaMIG 1.0
  - Throughout the document
- Useful new variables
- Additional examples
- Clarified ADaM vs. non-ADaM analysis datasets
- If an ADaM variable name for a concept is defined, it must be used
- Tables of variable name fragments
- Length of copied SDTM variables can be reduced to maximum length of actual values
- New *w* index in variable names

Notable Enhancements (continued)

- Clarified when and how labels can be modified
- Can skip in sequence, e.g. ANL02FL, ANL05FL
- TRTP not required in BDS - Any trt variable OK
- Clarified purpose of and relationships among PARAM, AVAL, and AVALC
- Clarified scope of statements; to apply within:
  - study, or dataset, or parameter
  - rows on which both variables in a mapping are populated
- Reinforced that PARCATy is not a qualifier of PARAM
  - PARAM maps many-to-one to PARCATy

Notable Enhancements (continued)

- Some changes in CDISC Core (Req, Cond, Perm)
- Expanded SRCDOM to allow ADaM dataset names, SRCSEQ to refer to new variable ASEQ
  - As in TTE document
- Example diagram of use of Phase, Period and Subperiod
- Recommended approach to multiple imputation
- Considerations for copying values onto a new record
- Appendix B, Revision History
  - Many more details than covered in this webinar


Analysis Datasets
ADaM Datasets
Non-ADaM Analysis Datasets
ADSL
BDS
OCCDS
OTHER
ADSL
ADLB*
ADAE*
ADMV*
PATP**
ADEFF*
AXEVT**
ADTTE*
* Example name of ADaM dataset
** Example name of dataset developed without following ADaM fundamental principles

ADSL: Corrections

TRxxPGyN	Type changed to Num
TRxxAGyN	Type changed to Num

ADSL: New Demographic Variables

ACTARM	Description of Actual Arm
REGIONy	Geographic Region y
REGIONyN	Geographic Region y (N)
AGEGRy	Pooled Age Group y
AGEGRyN	Pooled Age Group y (N)
AAGE	Analysis Age

ADSL: New Dose Variables

DOSExxP	Planned Treatment Dose for Period xx
DOSExxA	Actual Treatment Dose for Period xx
DOSExxU	Units for Dose for Period xx

ADSL: New Treatment Sequence Grouping Variables

TSEQPGy	Planned Pooled Treatment Sequence y
TSEQPGyN	Planned Pooled Treatment Sequence y (N)
TSEQAGy	Actual Pooled Treatment Sequence y
TSEQAGyN	Actual Pooled Treatment Sequence y (N)

ADSL: New Phase Variables

APHASEw	Description of Phase w
PHwSDT	Phase w Start Date
PHwSTM	Phase w Start Time
PHwSDTM	Phase w Start Datetime
PHwSDTF	Phase w Start Date Imputation Flag
PHwSTMF	Phase w Start Time Imputation Flag
PHwEDT	Phase w End Date
PHwETM	Phase w End Time
PHwEDTM	Phase w End Datetime
PHwEDTF	Phase w End Date Imputation Flag
PHwETMF	Phase w End Time Imputation Flag

ADSL: New Subperiod Variables

PxxSw	Description of Period xx Subperiod w
PxxSwSDT	Period xx Subperiod w Start Date
PxxSwSTM	Period xx Subperiod w Start Time
PxxSwSDM	Period xx Subperiod w Start Datetime
PxxSwSDF	Period xx Subper w Start Date Imput Flag
PxxSwSTF	Period xx Subper w Start Time Imput Flag
PxxSwEDT	Period xx Subperiod w End Date
PxxSwETM	Period xx Subperiod w End Time
PxxSwEDM	Period xx Subperiod w End Datetime
PxxSwEDF	Period xx Subper w End Date Imput Flag
PxxSwETF	Period xx Subper w End Time Imput Flag

ADSL: New Status Variables

EOSSTT	End of Study Status
EOSDT	End of Study Date
DCSREAS	Reason for Discontinuation from Study
DCSREASP	Reason Spec for Discont from Study
EOTSTT	End of Treatment Status
DCTREAS	Reason for Discontinuation of Treatment
DCTREASP	Reason Specify for Discont of Treatment
EOTxxSTT	End of Treatment Status in Period xx
DCTxxRS	Reason for Discont of Treat in Period xx
DCTxxRSP	Reason Spec for Disc of Trt in Period xx
EOPxxSTT	End of Period xx Status
DCPxxRS	Reason for Discont from Period xx
DCPxxRSP	Reason Spec for Discont from Period xx

ADSL: New Treatment Summary Variables

TRCMP	Treatment Compliance (%)
TRCMPGy	Treatment Compliance (%) Group y
TRCMPGyN	Treatment Compliance (%) Group y (N)
TRxxDURD	Treatment Duration in Period xx (Days)
TRxxDURM	Treatment Duration in Period xx (Months)
TRxxDURY	Treatment Duration in Period xx (Years)
TRTDURD	Total Treatment Duration (Days)
TRTDURM	Total Treatment Duration (Months)
TRTDURY	Total Treatment Duration (Years)

ADSL: New Death Variables

DTHDT	Date of Death
DTHDTF	Date of Death Imputation Flag
DTHCAUS	Cause of Death
DTHCAUSN	Cause of Death (N)
DTHCGRy	Cause of Death Group y
DTHCGRyN	Cause of Death Group y (N)

ADSL: Other New Date Variables

RFICDT	Date of Informed Consent
ENRLDT	Date of Enrollment
RFICyDT	Date of Informed Consent y
ENRLyDT	Date of Enrollment y
RANDyDT	Date of Randomization y
LSTALVDT	Date Last Known Alive

BDS: Corrections

COMPLRFL	Name changed from COMPRFL
COMPLPFL	Name changed from COMPPFL
ANRLO	Type changed to Num
ANRHI	Type changed to Num
AyLO	Type changed to Num
AyHI	Type changed to Num

BDS: Removed Variables
(will always be permissible)

ITTRFN	Intent-To-Treat Record-Level Flag (N)
SAFRFN	Safety Analysis Record-Level Flag (N)
FASRFN	Full Analysis Set Record-Level Flag (N)
PPROTRFN	Per-Protocol Record-Level Flag (N)
COMPRFN *	Completers Record-Level Flag (N)
ITTPFN	Intent-To-Treat Param-Level Flag (N)
SAFPFN	Safety Analysis Param-Level Flag (N)
FASPFN	Full Analysis Set Param-Level Flag (N)
PPROTPFN	Per-Protocol Parameter-Level Flag (N)
COMPPFN *	Completers Parameter-Level Flag (N)

* Note that in 1.1, names would start with COMPL instead of COMP

BDS: Deprecated Variable
(will always be permissible)

PARAMTYP	Variable will be removed in next version after 1.1

BDS: New Sequence Variable

ASEQ	Analysis Sequence Number

Supports datapoint traceability in child ADaM dataset to parent ADaM dataset via:

- SRCDOM=parent ADaM dataset name
- SRCVAR=parent ADaM variable name
- SRCSEQ=parent ASEQ

BDS: New Dose Variables

DOSEP	Planned Treatment Dose
DOSCUMP	Cumulative Planned Treatment Dose
DOSEA	Actual Treatment Dose
DOSCUMA	Cumulative Actual Treatment Dose
DOSEU	Treatment Dose Units

BDS: New Phase Variables

APHASEN	Phase (N)
PHSDT	Phase Start Date
PHSTM	Phase Start Time
PHSDTM	Phase Start Datetime
PHSDTF	Phase Start Date Imput. Flag
PHSTMF	Phase Start Time Imput. Flag
PHEDT	Phase End Date
PHETM	Phase End Time
PHEDTM	Phase End Datetime
PHEDTF	Phase End Date Imput. Flag
PHETMF	Phase End Time Imput. Flag

BDS: New Period Variables

APERSDT	Period Start Date
APERSTM	Period Start Time
APERSDTM	Period Start Datetime
APERSDTF	Period Start Date Imput. Flag
APERSTMF	Period Start Time Imput. Flag
APEREDT	Period End Date
APERETM	Period End Time
APEREDTM	Period End Datetime
APEREDTF	Period End Date Imput. Flag
APERETMF	Period End Time Imput. Flag

BDS: New Subperiod Variables

ASPER	Subperiod within Period
ASPERC	Subperiod within Period (C)
ASPRSDT	Subperiod Start Date
ASPRSTM	Subperiod Start Time
ASPRSDTM	Subperiod Start Datetime
ASPRSDTF	Subperiod Start Date Imput. Flag
ASPRSTMF	Subperiod Start Time Imput. Flag
ASPREDT	Subperiod End Date
ASPRETM	Subperiod End Time
ASPREDTM	Subperiod End Datetime
ASPREDTF	Subperiod End Date Imput. Flag
ASPRETMF	Subperiod End Time Imput. Flag

BDS: New Multinomial-Valued Criterion Evaluation Variables

MCRITy	Analysis Multi-Response Criterion y
MCRITyML	Multi-Response Criterion y Evaluation
MCRITyMN	Multi-Response Criterion y Eval (N)

BDS: (New) TTE Variables

STARTDTM	Time-to-Event Origin Datetime
STARTDTF	Origin Date Imputation Flag
STARTTMF	Origin Time Imputation Flag
CNSDTDSC	Censor Date Description

These variables were copied from the Time-to-Event document to add to the TTE variables already in IG 1.0

BDS: New Normal Range Variables

ANRLOC	Analysis Normal Range Lower Limit (C)
ANRHIC	Analysis Normal Range Upper Limit (C)
AyLOC	Analysis Range y Lower Limit (C)
AyHIC	Analysis Range y Upper Limit (C)
AyIND	Analysis Range y Indicator
ByIND	Baseline Analysis Range y Indicator

Acknowledgements

- ADaM Team
  - Many years of enormous unsung volunteer effort
  - Dozens of important contributors
- Susan Kenny, Team Lead 2006-2008
  - Set the team on the path to an Implementation Guide
  - Lead the initial work for IG 1.0
- Cathy Barrows, ADaM Leadership Team, retired
  - Indispensable co-lead and organizer for both versions
  - Original co-lead for IG 1.1
- Nate Freimark, Team Lead 2010-present
  - Interim co-lead for IG 1.1
- Sandra Minjoe, ADaM Leadership Team
  - Final co-lead for IG 1.1

ADaM Occurrence Data Structure (OCCDS) v1.0

CDISC Webinar, 2016-05-19

Sandra Minjoe
Data Standards Consulting
Accenture Accelerated R&D Services

Strength *through Collaboration*

OCCDS is an ADaM Structure

- There are 3 official ADaM structures
  - ADSL
  - BDS
  - OCCDS

- ADaMIG v1.1
  - Describes ADSL and BDS
  - Section 1.3 mentions that OCCDS is covered in this external document

OCCDS v1.0 Agenda

- Overview of the OCCDS structure
  - Comparison with BDS
  - Examples of appropriate uses
- OCCDS History
  - Predecessor documents
  - Connection to ADaMIG v1.1

What is OCCDS?

- OCCDS was developed specifically for occurrence analysis needs
- Occurrence analysis is the counting of subjects with a given record or term
  - Often includes a structured hierarchy of dictionary coding categories
- Examples include standard analyses of
  - Adverse Events
  - Concomitant Medications
  - Medical History

Example Analysis Need: Adverse Events

4.1 Analysis Display Example Layout

Table 4.1.1 Example of Summary of Treatment Emergent Adverse Events*

Table 14.2.7.1
Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Analysis Population: Safety

SYSTEM ORGAN CLASS Preferred Term	Treatment A (N = xxx) n (%)	Treatment B (N = xxx) n (%)
Number of subjects reporting at least one adverse event	x (x.x)	x (x.x)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		
At least one event	x (x.x)	x (x.x)
Anaemia	x (x.x)	x (x.x)
…	x (x.x)	x (x.x)
CARDIAC DISORDERS		
At least one event	x (x.x)	x (x.x)
Angina pectoris	x (x.x)	x (x.x)
Coronary artery disease	x (x.x)	x (x.x)
Ventricular tachycardia	x (x.x)	x (x.x)
Myocardial infarction	x (x.x)	x (x.x)
…	x (x.x)	x (x.x)
<Other SOCs and PTs>		

Example Analysis Need: Concomitant Medications

9.1 Analysis Display Example Layout

Table 9.1.1 Example of Summary of Concomitant Medications*

Table 14.1.5
Summary of Concomitant Medications by Medication Class and Preferred Term
Analysis Population: Safety

Medication Class/Preferred Term	Treatment A (N=4)	Treatment B (N=5)	Total (N=9)
Any Concomitant Medication	4 (100.0%)	4 (80.0%)	8 (88.9%)
ANALGESICS	2 (50.0%)	2 (40.0%)	4 (44.4%)
PARACETAMOL	2 (50.0%)	2 (40.0%)	4 (44.4%)
ANTIBACTERIALS FOR SYSTEMIC USE	1 (25.0%)	1 (20.0%)	2 (22.2%)
AMOXICILLIN	1 (25.0%)	1 (20.0%)	2 (22.2%)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	1 (25.0%)	2 (40.0%)	3 (33.3%)
IBUPROFEN	1 (25.0%)	2 (40.0%)	3 (33.3%)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	0	2 (40.0%)	2 (22.2%)
MONTELUKAST	0	1 (20.0%)	1 (11.1%)
SALBUTAMOL	0	2 (40.0%)	2 (22.2%)
NASAL PREPARATIONS	2 (50.0%)	0	2 (22.2%)
FLUTICASONE PROPIONATE	2 (50.0%)	0	2 (22.2%)
PSYCHOANALEPTICS	1 (25.0%)	0	1 (11.1%)
SERTRALIN	1 (25.0%)	0	1 (11.1%)

Example Analysis Need: Medical History

10.1 Analysis Display Example Layout

Table 10.1.1 Example of Summary of Medical History*

Summary of General Medical History Events Safety Population			
HISTORY CATEGORY **Body System** **Event**	**Active Drug** **(N=4)**	**Placebo** **(N=5)**	**Total** **(N=9)**
Any Medical History	3 (75.0%)	3 (60.0%)	6 (66.7%)
GASTROINTESTINAL	1 (25.0%)	0	1 (11.1%)
Gastrointestinal disorders	1 (25.0%)	0	1 (11.1%)
Abdominal pain	1 (25.0%)	0	1 (11.1%)
Gastroesophageal reflux disease	1 (25.0%)	0	1 (11.1%)
Nausea	1 (25.0%)	0	1 (11.1%)
HEMATOLOGICAL/LYMPHATIC	1 (25.0%)	0	1 (11.1%)
Blood and lymphatic system disorders	1 (25.0%)	0	1 (11.1%)
Anaemia	1 (25.0%)	0	1 (11.1%)
RESPIRATORY	3 (75.0%)	3 (60.0%)	6 (66.7%)
Immune system disorders	2 (50.0%)	3 (60.0%)	5 (55.6%)
Seasonal allergy	2 (50.0%)	3 (60.0%)	5 (55.6%)
Infections and infestations	1 (25.0%)	2 (40.0%)	3 (33.3%)
Upper respiratory tract infection	1 (25.0%)	2 (40.0%)	3 (33.3%)
Respiratory, thoracic and mediastinal disorders	1 (25.0%)	3 (60.0%)	4 (44.4%)
Asthma	1 (25.0%)	0	1 (11.1%)
Dyspnoea	0	3 (60.0%)	3 (33.3%)

Three Rules for OCCDS Use

1. There is no need for AVAL or AVALC
   - There are typically one or more records for each occurrence assessment
2. Occurrence is (often) coded via a dictionary
   - Typically includes a well-structured hierarchy of categories and terminology
   - Re-mapping this hierarchy to BDS variables PARAM and generic *CAT variables would lose the structure and meaning of the dictionary
3. Data content is typically not modified for analysis
   - There is no need for analysis versions of the variables that hold the dictionary hierarchy or category terms

Common Uses for OCCDS

- Standard analyses of
  - Adverse Events
  - Concomitant Medications
  - Medical History
- Other possible use cases
  - Clinical Events
  - Procedures
  - Substance Use
  - Inclusion/exclusion criteria occurrences
- There may be other uses, depending on the analysis need

Determining When to Use OCCDS

- Many (but not all) SDTM events and interventions class data are often analyzed as occurrences and thus should use OCCDS
  - Note: exposure data (EX) is often best analyzed with BDS, creating multiple analysis parameters
  - Lab events is an example of a findings SDTM class data analyzed as occurrences with OCCDS
- OCCDS is not designed for all categorical data
  - Example: questionnaire responses would never be mapped to a hierarchical dictionary, fit nicely in BDS, and should not use OCCDS
- Choice of ADaM dataset structure always depends on analysis need

OCCDS History

- May 2012
  - Analysis Data Model (ADaM) Data Structure for Adverse Event Analysis v1.0
- March 2014
  - Draft Occurrence Data Structure out for public comment
  - Abbreviation of “ODS” used at that time
- June 2015
  - Provisional release of OCCDS v1.0
  - Reflected all changes and corrections identified during comment period
  - Tied to some features of ADaMIG v.1.1, not yet released
- February 2016
  - Final release of v1.0

OCCDS vs. ADAE

- OCCDS is based on the document titled “Analysis Data Model (ADaM) Data Structure for Adverse Event Analysis”
  - Often called “ADaM ADAE document”
- OCCDS was developed to make ADAE content
  - More generic
  - Applicable to analysis of more than just adverse event data

OCCDS vs. ADAE Outline

- An early table in the OCCDS document explains the differences between OCCDS and ADAE:

Table 1.1.1: Differences between Data Structures

	Data Structure for Adverse Events Analysis	Data Structure for Occurrence Data
Applications	Only adverse events	Adverse events plus other types of data
ADaM version	ADaM v 2.1, ADaMIG v1.0	ADaM v 2.1, ADaMIG v1.1
SDTM version	SDTM v1.2, SDTMIG v3.1.2	SDTM v 1.4, SDTMIG v3.2
Dataset metadata class	ADAE	OCCURRENCE DATA STRUCTURE
ANLzzFL label	"Analysis Record Flag zz"	"Analysis Flag zz"
AOCCFL label	"1st Occurrence of Any AE Flag"	"1st Occurrence within Subject Flag"
Study Drug Dose at Onset	Variable name "DOSEAEON" and label "Study Drug at AE Onset"	Variable name "DOSEON" and label "Treatment Dose at Record Start"
Treatment Dose Units	Separate variables named "DOSAEONU" and "DOSECUMU"	Variable name "DOSEU" and label "Treatment Dose Units"
Cumulative Actual Treatment Dose	Variable name "DOSECUM" and label "Cumulative Study Drug Dose"	Variable name "DOSCUMA" and label "Cumulative Actual Treatment Dose"
Original or Prior Coding Variables	Use of "y" suffix to represent prior version	Use of "w" suffix to represent prior version

OCCDS vs. ADAE Details (1)

- OCCDS added variables not applicable to AEs
  - Example: WHO-Drug hierarchy
- OCCDS added new Controlled Terminology
  - Class = “OCCURRENCE DATA STRUCTURE”
- OCCDS is based on later versions of both ADaMIG and SDTMIG documents
  - References SDTM AE variables promoted from SUPPQUAL to the parent domain
  - Some OCCDS variable names make use of “w” index, introduced in ADaMIG v1.1

OCCDS vs. ADAE Details (2)

- Very few variable name (and label) changes

	ADAE	OCCDS
Study Drug Dose at Onset	Variable name “DOSEAEON” and label “Study Drug at AE Onset”	Variable name “DOSEON” and label “Treatment Dose at Record Start”
Treatment Dose Units	Separate variables named “DOSAEONU” and “DOSECUMU”	Variable name “DOSEU” and label “Treatment Dose Units”
Cumulative Actual Treatment Dose	Variable name “DOSECUM” and label “Cumulative Study Drug Dose”	Variable name “DOSCUMA” and label “Cumulative Actual Treatment Dose”

- Two other variable label changes

	ADAE	OCCDS
ANLzzFL	“Analysis Record Flag zz”	“Analysis Flag zz”
AOCCFL	“1st Occurrence of Any AE Flag”	“1st Occurrence within Subject Flag”

Choosing Documents

- If using ADaMIG v1.0
  - Use Analysis Data Model (ADaM) Data Structure for Adverse Event Analysis v1.0
  - Whenever possible, make use of variable names in OCCDS v1.0
  - Non-AE occurrence data is class “ADAM OTHER”
- If using ADaMIG v1.1
  - Use OCCDS v1.0
  - All occurrence data, including adverse events, is class “OCCURRENCE DATA STRUCTURE”

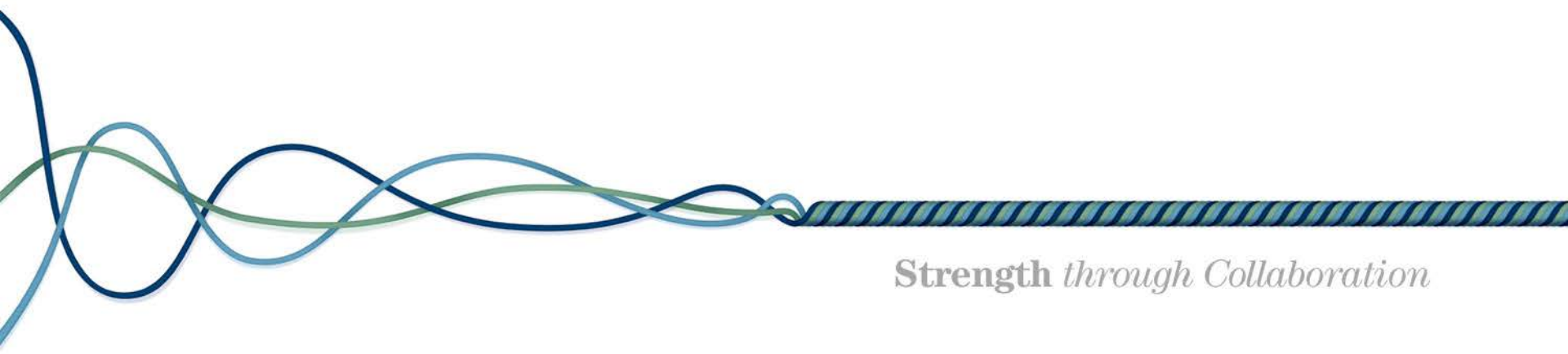
Acknowledgements

- Deb Bauer, ADAE document team lead
  - Lead the initial work
- ADaM OCCDS team
  - Created a lot of details, examples

Q&A

CDISC Online Education & Event Updates

John Ezzell, CDISC



UPCOMING NORTH AMERICA PUBLIC COURSES

Location	Dates	Courses Offered	Register by:	Early registration discount:	Host
North Chicago, IL	23-27 May	SDTM, CDASH, ADaM Primer, ADAM T&A	23 May	Expired	abbvie
Toronto, ON	24-27 May	SDTM, ADaM T&A, Define-XML	23 May	Expired	McDOUGALL SCIENTIFIC INSIGHTS YOU CAN TRUST
Durham, NC	20-24 June	SDTM, ADaM Primer, ADaM T&A, Define-XML	20 May	Expired	Duke Clinical Research Institute DUKE UNIVERSITY MEDICAL CENTER
Whippany, NJ	18-22 July	SDTM, CDASH, ADaM Primer, ADaM T&A	18 June	Expired	BAYER Bayer HealthCare
Minneapolis, MN	22-26 Aug	SDTM-MD, CDASH, ADaM Primer, ADaM T&A	22 Sep	Expired	MedNet Solutions

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UPCOMING EUROPE PUBLIC COURSES

Location	Dates	Courses Offered	Register by:	Early registration discount:	Host
Frankfurt, Germany	13-17 Jun	SDTM, ADaM Primer, ADaM T&A, Define-XML	13 May	14 Mar	ACCOVION
Brussels, Belgium	5-9 Sep	SDTM, CDASH, ADaM Primer, ADaM T&A	5 Aug	6 Jun	Business & Decision Life Sciences
Copenhagen, Denmark	Oct 2016	SDTM, SEND, ADaM Primer, ADAM T&A, Defne-XML	1 Sep	3 Jul	SCUBED
Basel, Switzerland	7-11 Nov	SDTM, ADaM Primer, ADaM T&A, Define-XML	7 Oct	7 Aug	ACTELION

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UPCOMING ASIA PUBLIC COURSES

Location	Dates	Courses Offered	Register by:	Early Registration Discounts	Host
Tokyo, Japan	30 May – 3 Jun	See web.	13 May	26 Feb	CDISC
Osaka, Japan	12-16 Sep	See web.	12 Aug	12 June	EXICARE CAC EXICARE Corporation
Beijing, China	18-21 Oct	TBA	TBA	TBA	TBA
Shanghai, China	24-27 Oct	TBA	TBA	TBA	TBA
Tokyo, Japan	5-9 Dec	TBA	TBA	TBA	TBA

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Upcoming Webinars

Presenter	Topic	Webinar Date
Fred Wood, Accenture	The Need for Human Intelligence in Assessing SDTM Conformance	Jun 9, 2016
Bernice Yost, CDISC Kathleen Mellars, Independent Lorraine Spencer, Takeda Michael J Ward, Lilly Trisha Simpson, UCB	CT Quarterly Updates & CDASH V2 Public Review	Jun 16, 2016

Webinar details and registration at www.cdisc.org/webinars

Any more questions?

Thank you for attending this webinar.

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